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(43) Date of A Publication 29.03.1995

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(22) Date of Filing 22.09.1993

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(51) INT CL⁶
A61M 5/32

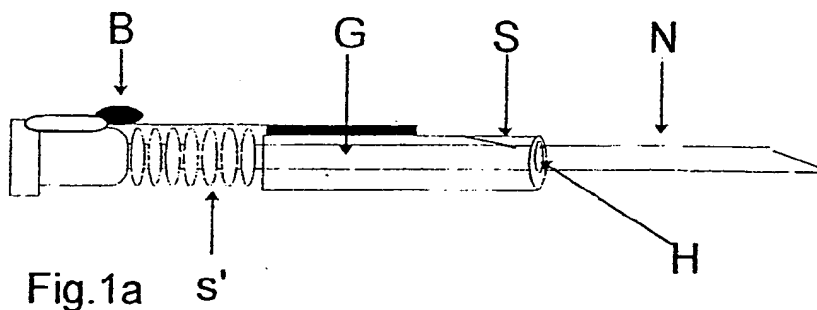
(52) UK CL (Edition N)
A5R RGG

(56) Documents Cited
GB 2262451 A GB 2252046 A WO 90/07349 A1
US 5181524 A US 3884230 A

(58) Field of Search
UK CL (Edition L) A5R RGG
INT CL⁵ A61M 5/32
ONLINE DATABASES: WPI

(54) The integral hypodermic needle guard

(57) The integral hypodermic needle guard is a device either produced as a component of a hypodermic needle or one that can be attached to the needle prior to its use. The guard can be used immediately afterwards to cover the hypodermic needle tip and render the needle tip safe. An example is described of a guard G connected to the hub of the needle N by a coiled spring S'. After the needle is removed from the skin the operator releases the coiled spring which is compressed by a locking device (L, Fig. 2b) by depressing button B and extends the guard over the end of the needle. The needle tip is forced into a cleft between the wall of the guard and its end by a straight spring S in the base of the guard. The guard is maintained in position by the force of the extended coiled spring.



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GB 2 282 069 A

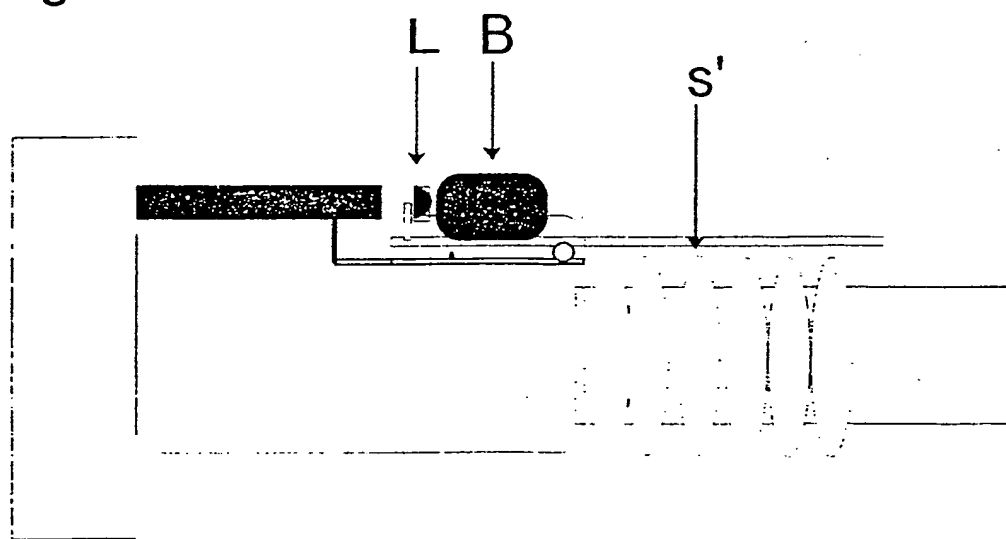
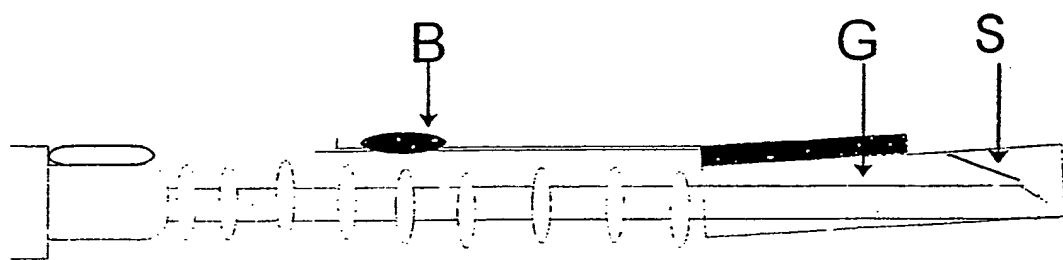
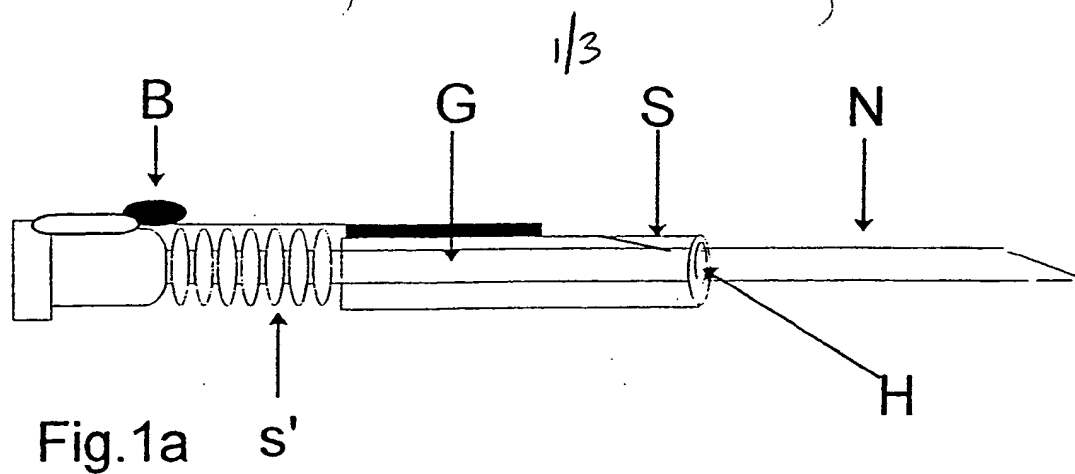
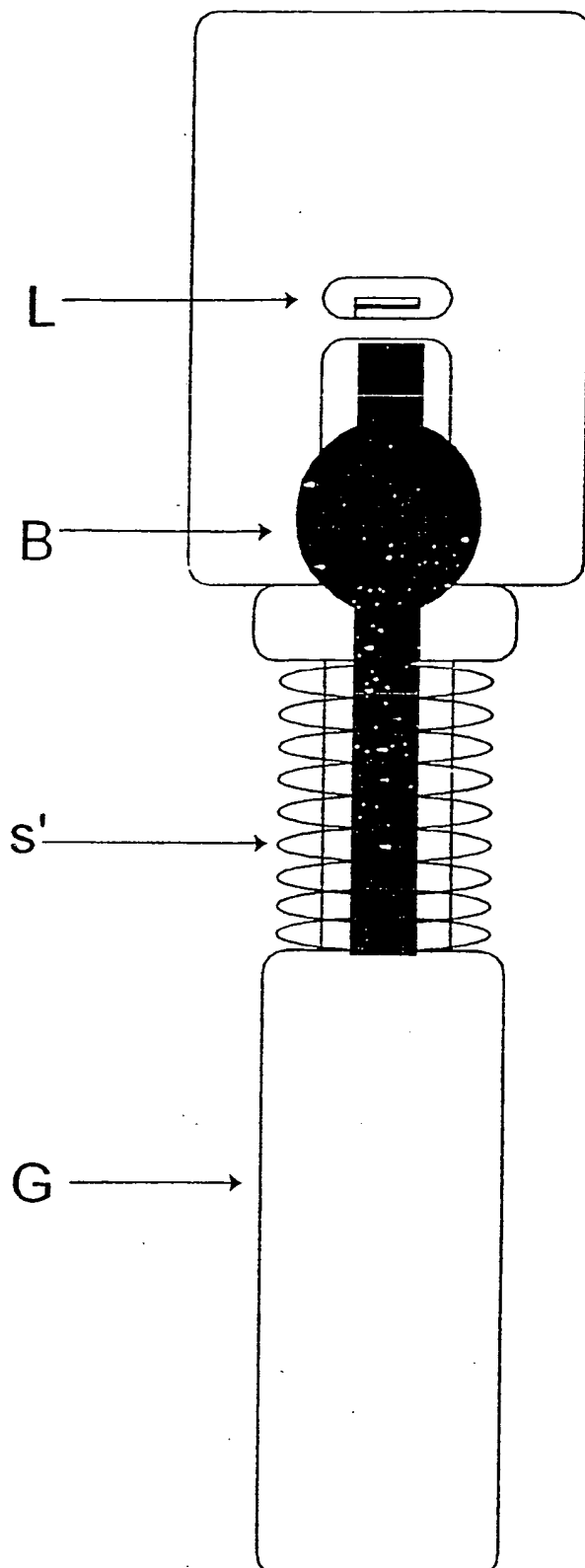
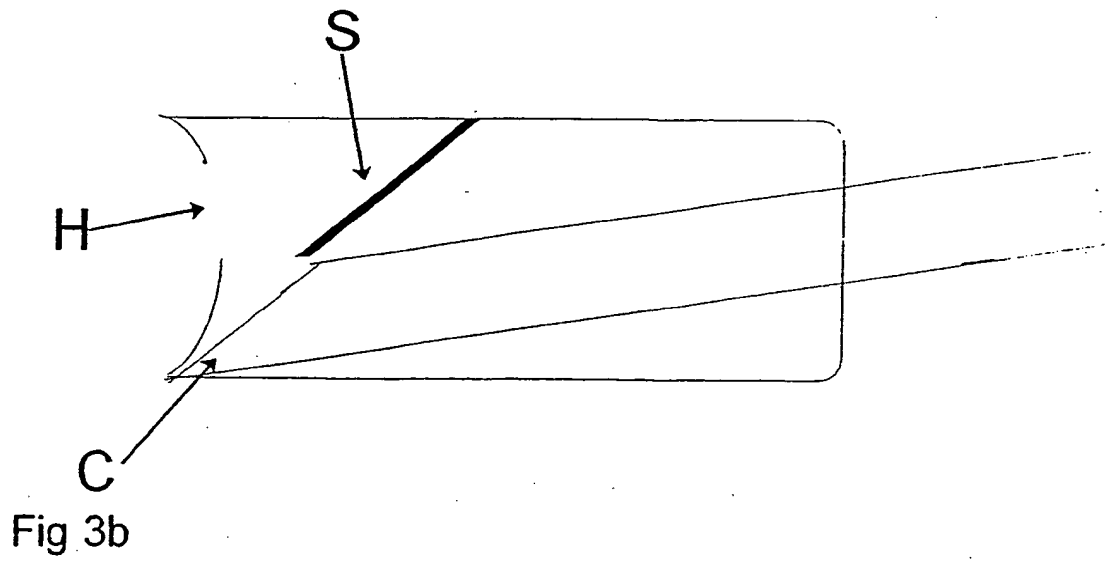
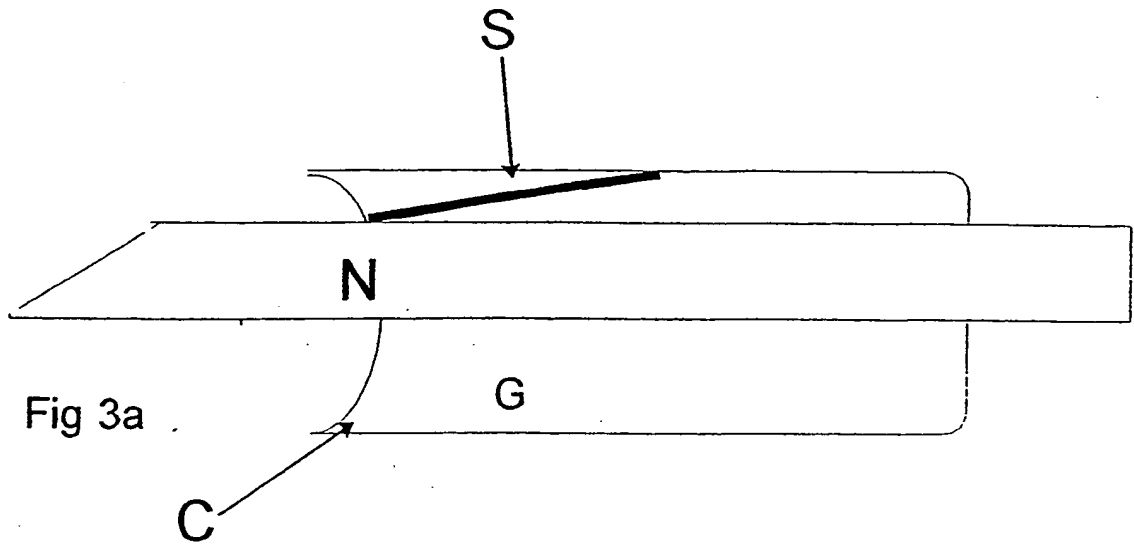


Fig.2b.



3/3



The Integral Hypodermic Needle Guard

A device either a component of a hypodermic needle or a part that can be attached to the hypodermic needle prior to use (integral at time of use) which can be used as a guard to cover the needle tip immediately after use and so prevent any possibility of a needle stick injury.

Needle stick injuries are always a worry for medical staff as such an injury could transmit viral infections. With the HIV virus such an injury could cause a life threatening disease. To prevent such injuries medical staff wear gloves; however the sharp point of the hypodermic needle can easily penetrate these. Needle stick injuries may occur when they try to cover the needle after use, missing the sheath and pricking their fingers. In the emergency situation staff do not have to resheath or throw away used needles and they can be left lying around with the potential to cause a needle stick injury. Once the needle is thrown away the disposal box might be opened or spilt and a member of staff could be injured whilst tidying up the contents.

The integral Hypodermic Needle Guard was invented to ensure that immediately after blood has been taken the operator can cover the needle tip so preventing any possibility of further needlestick injuries.

The present invention provides a guard attached to the needle which can be used immediately after use to cover and protect the needle tip.

The guard can be a device made of any suitable material which is part of or can be attached to the needle prior to use which can be used by the operator immediately after the needle has been withdrawn from the injection site.

For example a circular sheath is described which encircles the shaft of the needle. The sheath could be made of any suitable material. The sheath has a concave circular disc attached to one end. A hole the diameter of the needle is made in one half of the circular disc. The needle passes through the sheath over the metal spring and out through the hole in the disc. The flat part of the needle tip has to be resting at the centre of the disc. The sheath and the disc combined forms the guard. As the guard is pushed over the end of the needle a small spring in the base of the guard pushes the needle tip up into the cleft between the disc and the sheath. The guard can be maintained in this position by several methods; for example a coiled spring attached to the hub of the needle and to the sheath so when extended the extended coiled spring would pull the guard back on the needle tip.

An example of the Integral Hypodermic Needle Guard with reference to the accompanying drawing in which:

Figure 1a Shows the whole needle plus guard(the outline of the guard is drawn). A coiled spring is attached to the hub of the needle and to the sheath.

Figure 1b Shows the sheath extended over the end of the needle. A spring in the base of the guard forces the needle tip into the cleft shown. The extended coiled spring will pull back on the guard and maintain the guard in place.

Figure 2a Shows the side view of the needle hub showing a clip mechanism keeping the spring compressed.

Figure 2b Shows the view from the top of the locking mechanism keeping the coiled spring compressed. The spring is released by compressing the button; using the button the guard is advanced by pushing it over the end of the needle against the force of the extended coiled spring.

Figure 3a Shows longitudinal section through the sheath and the needle. Note the spring at the base of the guard and the site of the hole from the front of the guard. The needle has to be positioned so the flat part of the needle tip lies against the middle of the hole at the front of the guard.

Figure 3b Shows a longitudinal section of the needle and the sheath after the sheath has been pushed over the needle tip. The point of the needle is trapped in the cleft between the sheath and the concave disc attached to the base of the sheath.

Referring to the drawing the guard is an integral part of the hypodermic needle so that the operator can push the guard (G in Fig 1) over the end of the needle so that the guard safely covers the point of the hypodermic needle tip.

The guard illustrated in Fig 1 is attached to the needle hub by a spring. The spring is kept compressed by a locking device (L in Fig 2a and 2b). The spring is released by depressing the button (B in Fig 2a and 2b). Once blood has been taken the operator releases the spring by pressing the button. The operator then pushes the guard over the end of the needle tip using the button provided.

The guard illustrated is a cylinder with a concave disc attached to the base at one end. The needle passes through the sheath and out through a hole in the concave disc which is positioned so that one edge of the hole (H in Fig 1a and Fig 2a) is at or beyond the centre of the disc. The flat side of the needle tip has to lie next to the central part of the hole.

When the guard is pushed over the tip of the needle the needle tip will slide into the cleft (C in Fig 3a) at the base of the guard. The needle is forced into the cleft by the use of a metal spring (S in Fig 3) positioned in the base of the guard which maintains the needle in the cleft. The guard is prevented from falling off by the force of the extended coiled spring (s' in fig 1b) which pulls the needle back and also keeps the guard in position so that the needle tip is covered and secured.

Claims

1. A device part of, or attached prior to use to, a hypodermic needle which can be used as a guard to cover the needle tip immediately after use. The device is therefore integral with the hypodermic needle at time of use.
2. The guard as in claim 1 can be made in various shapes of various materials.
3. The guard as claimed in claims 1 and 2 can be maintained in its position over the point of the hypodermic needle by various mechanisms following withdrawal from the injection site.
4. The device as claimed in preceding claims allows the operator to render safe the needle tip without any risk to the operator of a needle stick injury.

Patents Act 1977
Examiner's report to the Comptroller under Section 17
The Search report)

Application number
GB 9319510.5

Relevant Technical Fields

- (i) UK Cl (Ed.M) A5R (RGG)
(ii) Int Cl (Ed.5) A61M 5/32

Search Examiner
MISS M M KELMAN

Date of completion of Search
26 November 1993

Databases (see below)

(i) UK Patent Office collections of GB, EP, WO and US patent specifications.

Documents considered relevant following a search in respect of Claims :-
1 to 4

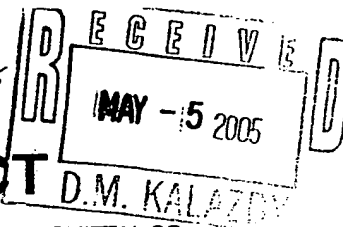
(ii) ONLINE DATABASES: WPI

Categories of documents

- X: Document indicating lack of novelty or of inventive step. P: Document published on or after the declared priority date but before the filing date of the present application.
Y: Document indicating lack of inventive step if combined with one or more other documents of the same category. E: Patent document published on or after, but with priority date earlier than, the filing date of the present application.
A: Document indicating technological background and/or state of the art. &: Member of the same patent family; corresponding document.

Category	Identity of document and relevant passages		Relevant to claim(s)
X	GB 2262451 A	(TZE CHUEN NG) - see the claims and Figure 5	1 to 4
X	GB 2252046 A	(STEYN) - see the claims and Figure 1	1 to 4
X	WO 90/07349 A1	(VADHER) - see page 18 line 6 to page 22, line 30	1 to 4
X	US 5181524 A	(MEDICAL SAFETY PRODUCTS) - see column 6, line 34 to column 7, line 20	1 to 4
X	US 3884230 A	(WULFF) - see Figures 1 and 2	1 to 4

Databases: The UK Patent Office database comprises classified collections of GB, EP, WO and US patent specifications as outlined periodically in the Official Journal (Patents). The on-line databases considered for search are also listed periodically in the Official Journal (Patents).

to DMF 5/5/05
Sew

From the INTERNATIONAL SEARCHING AUTHORITY

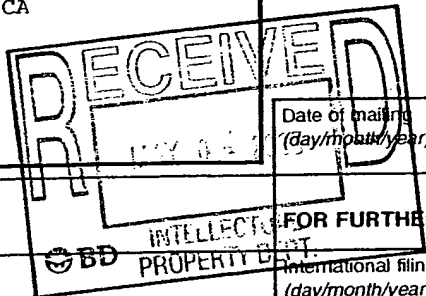
To:
 BECTON, DICKINSON AND COMPANY
 Attn. Hight, David W.
 1 Becton Drive
 Franklin Lakes, NJ 07417-1880
 UNITED STATES OF AMERICA

NOTIFICATION OF TRANSMITTAL OF
 THE INTERNATIONAL SEARCH REPORT AND
 THE WRITTEN OPINION OF THE INTERNATIONAL
 SEARCHING AUTHORITY, OR THE DECLARATION
 Response Due: 7/2/05

Stat:



(PCT Rule 44.1)



Date of mailing
 (day/month/year)

02/05/2005

Applicant's or agent's file reference

P-6137.70

FOR FURTHER ACTION

See paragraphs 1 and 4 below

International application No.

PCT/US2005/000978

International filing date
 (day/month/year)

13/01/2005

Applicant

BECTON, DICKINSON AND COMPANY

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the International Search Report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
 1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
- ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90bis.1 and 90bis.3, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until **30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the *PCT Applicant's Guide*, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the International Searching Authority



European Patent Office, P.B. 5818 Patentlaan 2
 NL-2280 HV Rijswijk
 Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
 Fax: (+31-70) 340-3016

Authorized officer

Michael Wicha

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under article 19. The Notes are based on the requirements of the Patent Cooperation Treaty, the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. For more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule", and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended?

Under Article 19, only the claims may be amended.

During the international phase, the claims may also be amended (or further amended) under Article 34 before the International Preliminary Examining Authority. The description and drawings may only be amended under Article 34 before the International Examining Authority.

Upon entry into the national phase, all parts of the international application may be amended under Article 28 or, where applicable, Article 41.

When?

Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).

Where not to file the amendments?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How?

Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

The amendments must be made in the language in which the international application is to be published.

What documents must/may accompany the amendments?

Letter (Section 205(b)):

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confused with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must be in English or French, at the choice of the applicant. However, if the language of the international application is English, the letter must be in English; if the language of the international application is French, the letter must be in French.

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

1. [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
2. [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
4. [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the same time of filing the amendments with the International Bureau, also file a copy of such amendments with the International Preliminary Examining Authority (see Rule 62.2(a), first sentence).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, where upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see Volume II of the PCT Applicant's Guide.

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference P-6137.70	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US2005/000978	International filing date (day/month/year) 13/01/2005	(Earliest) Priority Date (day/month/year) 20/01/2004
Applicant BECTON, DICKINSON AND COMPANY		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 5 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ The international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box II).

3. ☐ **Unity of invention is lacking** (see Box III).

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. 1

☒ as suggested by the applicant.

☐ as selected by this Authority, because the applicant failed to suggest a figure.

☐ as selected by this Authority, because this figure better characterizes the invention.

- b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2005/000978

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

A medical device for delivering a medicament to a patient includes a syringe assembly having a barrel (24) defining a reservoir containing the medicament, a needle cannula (26) coupled to a forward end of the barrel, and a plunger having a stopper positioned in the barrel and movable into the barrel to cause the medicament to be expelled. The medical device also includes a cap (22) arranged on, and slidable over, the needle cannula from a first position in which the forward tip of the needle cannula is exposed, to a second position in which the forward tip of the needle cannula is covered by the cap. An actuation mechanism connected to the cap includes an urging member coupled to the barrel and the cap for urging the cap toward the second position. A trigger element releasably secures the urging member in a charged state and releasably secures the cap in the first position. The trigger element is actuatable to release the cap by either manual actuation or by interaction with the thumb pad.

INTERNATIONAL SEARCH REPORT

International Application No.
PCT/US2005/000978A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61M5/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61M

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2003/028171 A1 (DEHARDE LAWRENCE G ET AL) 6 February 2003 (2003-02-06)	1-11, 13, 21-31, 34-36
Y	paragraph '0061! - paragraph '0076!; figures 1-11	12, 14-20, 32, 33
X	US 5 312 372 A (DEHARDE ET AL) 17 May 1994 (1994-05-17) column 5, line 13 - column 6, line 45; figures 1-12	1, 21-23, 34-36
X	GB 2 282 069 A (ROBERT CHRISTOPHER GUY * BRACCHI) 29 March 1995 (1995-03-29) abstract; figures 1-3b	1, 20-23, 33-36
	-/--	

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

* Special categories of cited documents:

A document defining the general state of the art which is not considered to be of particular relevance

E earlier document but published on or after the international filing date

L document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

O document referring to an oral disclosure, use, exhibition or other means

P document published prior to the international filing date but later than the priority date claimed

T later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

X document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

Y document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

Z document member of the same patent family

Date of the actual completion of the international search

18 April 2005

Date of mailing of the international search report

02/05/2005

Name and mailing address of the ISA

European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,
Fax: (+31-70) 340-3016

Authorized officer

Björklund, A

INTERNATIONAL SEARCH REPORT

International Application No
PCT/US2005/000978

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5 342 320 A (CAMERON ET AL) 30 August 1994 (1994-08-30) figures 8-11 -----	1, 21-23, 34-36
Y	US 5 026 356 A (SMITH ET AL) 25 June 1991 (1991-06-25) figures 1-7 -----	12
Y	US 2002/065488 A1 (SUZUKI HITOSHI ET AL) 30 May 2002 (2002-05-30) figures 14-18, 20-22, 27-30, 34-36 -----	14-20, 32, 33

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No.

PCT/US2005/000978

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
US 2003028171	A1	06-02-2003	NONE	
US 5312372	A	17-05-1994	US 5215534 A AT 133343 T AU 657817 B2 AU 2965392 A CA 2084353 A1 DE 69207882 D1 DE 69207882 T2 EP 0549382 A1 MX 9206768 A1	01-06-1993 15-02-1996 23-03-1995 03-06-1993 03-06-1993 07-03-1996 05-09-1996 30-06-1993 01-06-1993
GB 2282069	A	29-03-1995	NONE	
US 5342320	A	30-08-1994	NONE	
US 5026356	A	25-06-1991	NONE	
US 2002065488	A1	30-05-2002	JP 2002191695 A US 2005038399 A1	09-07-2002 17-02-2005

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/US2005/000978

International filing date (day/month/year)
13.01.2005

Priority date (day/month/year)
20.01.2004

International Patent Classification (IPC) or both national classification and IPC
A61M5/32

Applicant
BECTON, DICKINSON AND COMPANY

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☒ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2005/000978

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. II Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43bis.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2005/000978

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	12,14-20,32-33
	No: Claims	1-11,13,21-31,34-36
Inventive step (IS)	Yes: Claims	
	No: Claims	1-36
Industrial applicability (IA)	Yes: Claims	1-36
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

**Reasoned statement with regard to novelty, inventive step or industrial applicability;
citations and explanations supporting such statement**

1. Reference is made to the following documents:

- D1: US 2003/028171 A1 (DEHARDE LAWRENCE G ET AL) 6 February 2003 (2003-02-06)
- D2: US-A-5 312 372 (DEHARDE ET AL) 17 May 1994 (1994-05-17)
- D3: GB-A-2 282 069 (ROBERT CHRISTOPHER GUY BRACCHI) 29 March 1995 (1995-03-29)
- D4: US-A-5 342 320 (CAMERON ET AL) 30 August 1994 (1994-08-30)
- D5: US-A-5 026 356 (SMITH ET AL) 25 June 1991 (1991-06-25)
- D6: US 2002/065488 A1 (SUZUKI HITOSHI ET AL) 30 May 2002 (2002-05-30)

2. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-11, 13, 21-31, 34-36 is not new in the sense of Article 33(2) PCT.

2.1. The document D1 discloses (the references in parentheses applying to this document):

A medical device for delivering a medicament to a patient (fig. 6A), comprising:
a syringe assembly comprising:

a barrel having a forward end and a rear end defining a reservoir within which the medicament may be contained (fig. 6A);

a needle cannula having a forward tip and being coupled to said forward end of said barrel and in fluid communication with said reservoir (fig. 6A); and

a plunger having a first end with a stopper positioned in said reservoir and a second end having a thumb pad for receiving medicament delivery pressure for causing said plunger to move within said reservoir to cause the medicament to be expelled from said reservoir (fig. 6A);

a cap arranged on said needle cannula and slidable along said needle cannula from a first position in which said forward tip of said needle cannula is exposed, to a second position in which said forward tip of said needle cannula is covered by said cap (figs. 6A-B); and
an actuation mechanism connected to said cap, said actuation mechanism having an

urging member coupled to said barrel and said cap, and a trigger element releasably securing said urging member in a charged state and releasably securing said cap in said first position, said trigger element being actuatable to release said urging member and said cap by one of manual actuation or interaction with said thumb pad (figs. 6A-B, [0072]-[0073])

The subject-matter of claim 1 is therefore not new (Article 33(2) PCT).

2.2. Documents D2-D4 (see references in search report) also discloses the subject-matter of claim 1 (Article 33(2) PCT).

2.3. The same reasoning applies, mutatis mutandis, to the subject-matter of the corresponding independent claims 23 and 36, which therefore are also considered not new (Article 33(2) PCT).

3. Dependent claims 2-22, 24-35 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, for the following reasons:

The features of claims 2-22, 24-35 merely define trivial design options for latching means, springs, materials etc which are known in the art, see documents D1-D6 and the corresponding passages cited in the search report.

Re Item VII

Certain defects in the international application

4. Claim 1 is not drafted in the two-part form (Rule 6.3(b) PCT) and none of the claims are provided with reference signs (Rule 6.2(b) PCT).

5. Document D1 is not mentioned in the description (Rule 5.1(a)(ii) PCT).

Re Item VIII

Certain observations on the international application

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)**

International application No.

PCT/US2005/000978

6. Claims 1, 23 and 36 have been drafted as independent claims and have at least partly overlapping scope. Drafting such a plurality of independent claims with overlapping scope makes it impossible to clearly delimit the subject matter which could represent the invention for which protection is sought, so that the claims as a whole fail to comply with the clarity and conciseness requirements of Article 6 PCT.

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